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| APPLICATION NO.                                                     | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---------------------------------------------------------------------|-------------|-------------------------|-------------------------|------------------|
| 10/629,934                                                          | 07/29/2003  | Verivada Chandrasekaran | 10527-410002            | 9045             |
| 26161                                                               | 7590        | 10/13/2006              | EXAMINER                |                  |
| FISH & RICHARDSON PC<br>P.O. BOX 1022<br>MINNEAPOLIS, MN 55440-1022 |             |                         | GHERBI, SUZETTE JAIME J |                  |
|                                                                     |             |                         | ART UNIT                | PAPER NUMBER     |
|                                                                     |             |                         | 3738                    |                  |

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                                       |  |
|------------------------------|-------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/629,934 | Applicant(s)<br>CHANDRASEKARAN ET AL. |  |
|                              | Examiner<br>Suzette J. Gherbi | Art Unit<br>3738                      |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.  
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4-12 and 43-52 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1,4-12 and 43-52 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1 Applicant's RCE and amendment and remarks dated 6/9/06 have been received in application serial number 10/629,934.

### ***Response to Arguments***

2. Applicant's arguments with respect to claims 1, 4-12, 43-51 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4-10, 12, 43-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Callol et al. 6,174,329. Callol et al discloses the invention as claimed noting figures 1-7 comprising: a first portion (10) and a second portion disposed outwardly of the first portion and having a first layer including a radiopaque material (this could be any of the metals listed in col. 5, lines 55-57 ie. tantalum) that is more radiopaque than the first portion; a second layer comprising an alloy (alloy simply means more two or more mixed metals) comprising the radiopaque material and a second material and a third layer comprising an oxidized form of the alloy. These

limitations are met (see col. 5, line 56, col. 6, lines 35-37) because col. 6, lines 47-54 state that the stent 10 (which is the first portion) is covered by a radiopaque coating (40) which may be loaded with radiopaque agents such as barium, titanium oxide and further multiple layers of the protective layer can be applied to the stent. The claims as written with the term "comprising" do not "limit" the materials and thus may include other materials. It is inherent (for example see application 2002/0138136 section [0029]"stable native oxides are formed) that materials that are mixed form alloys and if titanium and tantalum are alloys then an oxide is formed (see col. 6, line 50) that it would provide an oxidized form.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. in view of Roth 2004/0054399. Callol et al. has been disclosed above however Callol et al. does not specify a drug-releasing layer. Roth teaches a stent covered/layered with radiopaque material with a drug releasing layer (see [0032]). It

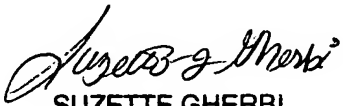
would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Callol et al. and incorporate therapeutic agents in the layers as taught by Roth in order to treat the vessel intima upon implantation and expansion of the device.

### ***Response to Arguments***

6. Applicant's arguments filed 6/9/06 have been fully considered but they are not persuasive. The examiner have give another rejection under Callol. Applicant contends that Callol et al. does not suggest a layer comprising an alloy of titanium and tantalum. It is the examiners opinion that the office action is correct. Callol teaches the limitations as claimed specifically (noting claims 1 and 12) Collol has a second portion having a first layer which is a radiopaque layer of a metal; a second layer called the protective layer/coating (40); wherein the protective layer/coating comprises an alloy (which is a titanium alloy even though claims 1 and 12 are not limited by titanium nor tantalum) and a second material (see col. 6, lines 24-54) wherein the second material can be a polymer loaded with the alloy. Callol further states that multiple layers loaded with radiopaque agents may be utilized. The applicants use of the word "comprising" does not mean that additional materials can't be present. Therefore, applicant's arguments are not convincing and the office action deemed proper.

**Conclusion**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.
8. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.
9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
SUZETTE GHERBI  
PRIMARY EXAMINER  
TECHNOLOGY CENTER 3700  
Suzette J-J Gherbi  
04 October 2006